

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG CO., INC.,

On behalf of itself and all others similarly
situated,

Plaintiffs,

v.

SANOFI-AVENTIS, SANOFI-AVENTIS U.S.
LLC, and AVENTIS PHARMACEUTICALS,
INC.,

Defendant.

No. 07 Civ. 7343

PUBLIC VERSION:

CONFIDENTIAL INFORMATION

REDACTED

DECLARATION OF JEFFREY J. LEITZINGER, PH.D.

Econ One Research, Inc.

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Suite 501
805 15th Street, N.W.
Washington, D.C. 20005
(202) 783-7878
fax (202) 289-6452

Suite 100
555 University Avenue
Sacramento, California 95825
(916) 576-0366
fax (916) 576-0365

5th Floor
601 West 5th Street
Los Angeles, California 90071
(213) 624-9600
fax (213) 624-6994

Suite 2825
Three Allen Center
333 Clay Street
Houston, Texas 77002
(713) 228-2700
fax (713) 228-3296

Suite 230
106 E. 6th Street
Austin, Texas 78701
(512) 476-3711
fax (512) 476-9712

I. Introduction and Qualifications

I am an economist and President of Econ One Research, Inc., an economic research and consulting firm with offices in Los Angeles, Washington D.C., Sacramento, Austin, and Houston. I have masters and doctoral degrees in economics from UCLA and a bachelor's degree in economics from Santa Clara University. While at UCLA, one of my areas of concentration was industrial organization, which involves the study of markets, competition, antitrust and other forms of regulation.

During the past 27 years of my professional career, industrial organization has remained the principal focus of much of my work. I have worked on numerous projects relating to antitrust economics, including analyzing issues involving market power, market definition, and the competitive effects of firm behavior. I also have frequently assessed damages resulting from anticompetitive conduct and have substantial experience in the calculation of damages in class action litigation. Additionally, I have significant experience with economic issues related to class certification in antitrust contexts.

I have testified as an expert economist in state and federal courts and before a number of regulatory commissions. A more detailed summary of my training, past experience and prior testimony is shown in Exhibit 1.

With respect to the pharmaceutical industry, I am familiar with the economic and academic literature on the subject of generic competition and impaired generic competition. I also have specific experience making economic assessments of the effects of AB-rated¹ generic competition in pharmaceutical markets. I have previously analyzed impact and damages issues, as well as issues relating to the allocation of aggregate damages to individual class members, in a number of antitrust cases that involve allegations very similar to this case -- *i.e.*, class actions involving direct purchasers of brand-name drugs who were overcharged as a result of impaired generic competition. Exhibit 1 lists these engagements.

For example, in the Relafen case (*In re: Relafen Antitrust Litigation*, Master File No. 01-12239-WGY (D. Mass.)), I submitted three reports in which I (i) evaluated market power under Section 2 of the Sherman Act, as well as relevant market issues, (ii) estimated aggregate overcharge damages to the direct purchaser class, and (iii) rebutted arguments made by the defense expert relating to class certification. The court granted class certification, and the

¹ "AB-rated" is a term the United States Food and Drug Administration ("FDA") uses to classify generic drug products that have been found to be therapeutically equivalent to the branded counterpart. An AB-rated generic may be freely substituted for its branded counterpart at the pharmacy level without the prescribing physician's permission in most states. The FDA lists such substitutable drugs in its "Orange Book," the formal title of which is *Approved Drug Products With Therapeutic Equivalence Evaluations*. "Therapeutically equivalent" is a technical term for products that meet certain criteria including safety and efficacy, "pharmaceutical equivalence," "bioequivalence," and labeling and manufacturing standards. The definitions of therapeutic equivalence, pharmaceutical equivalence, and bioequivalence are listed in Sections 1.2 and 1.7 of the FDA's "Orange Book". The "FDA Orange Book" can be found at <http://www.fda.gov/cder/orange/default.htm>.

Relafen direct purchaser class ultimately settled their claims for \$175 million. For purposes of that settlement, I submitted a report setting forth the damages methodology I employed, an allocation methodology and the results based upon application of my proposed methodologies to the claimant data. The damages and allocation methodologies and results were approved by the court.

In the *Cardizem* case (*In re: Cardizem CD Antitrust Litigation*, MDL No. 1278 (E.D. Mich.)), I prepared an analysis of aggregate, class-wide damages incurred by a class of direct purchasers for purposes of mediation and settlement. The direct purchaser class (which was certified by the court) settled their claims for \$110 million. I also prepared an analysis regarding the allocation of settlement proceeds among class members. The court approved that analysis.

I performed a similar role in the *Buspirone* case (*In re: Buspirone Patent & Antitrust Litigation*, MDL No. 1413 (S.D.N.Y.)). In connection with the \$220 million settlement of the direct purchaser class claims in that case, I prepared a report analyzing aggregate damages to the direct purchaser class and proposed a damages allocation method. This report was submitted to the court in support of the motion to approve the class settlement and proposed allocation plan and was approved as fair and reasonable.

In *In re: Remeron Direct Purchaser Antitrust Litigation*, No. 03-CV-0085 (D.N.J.), I submitted a report in support of class certification. The class

certification issues I addressed included (i) the likely impact of a delay in generic competition on a class of direct purchasers of the branded antidepressant Remeron, (ii) the availability of economic methodologies and evidence common to all class members that would demonstrate impact in the form of overcharges, and (iii) whether overcharge damages could be calculated on a class-wide, aggregate basis using reliable methodologies. I also submitted an expert report addressing the issues of monopoly power, market definition, and aggregate overcharge damages, and a rebuttal report on those subjects. Finally, I submitted a proposed allocation plan to the court in support of settlement. In *Remeron*, the direct purchaser class claims were settled for \$75 million and the court approved my damages and allocation methodologies as fair and reasonable.

In the case captioned *In re: TriCor Direct Purchaser Antitrust Litigation*, C.A. No. 05-340 KAJ (D. Del.), I submitted a report relating to class certification issues, including the availability of class-wide economic evidence and methodologies that would demonstrate class-wide impact and whether damages could be calculated on an aggregate basis. I also submitted two expert reports addressing relevant market/market power and aggregate class overcharge damages.

In the case captioned *In re: Meijer, Inc. et al. v. Warner Chilcott Holdings III, Ltd., et al.*, No. 05 Civ. 2195 CKK (D.D.C.), I submitted two

declarations relating to class certification issues. In particular, I discussed the availability of economic methodologies and evidence common to all class members that would demonstrate impact in the form of overcharges and whether overcharge damages could be calculated on a class-wide aggregate basis using reliable methodologies. I also submitted two expert reports addressing the aggregate class overcharge damages.

In the case captioned *In re: Nifedipine Antitrust Litigation*, (D.D.C.) I submitted a report and a rebuttal report relating to class certification issues, including the availability of class-wide economic evidence and methodologies to prove impact and aggregate overcharge damages. I also submitted an expert report addressing relevant market/market power and aggregate class overcharge damages.

Econ One is being compensated for the time I spend on this matter at my normal and customary rate of \$575 per hour. Econ One is also being compensated for the time spent by my research staff on this project at their normal and customary hourly rates.

II. Factual Overview

I understand that the Complaint² in this matter was filed by Louisiana Wholesale Drug Company, Inc. ("Plaintiff"), on behalf of itself and a

² The Complaint to which I refer is dated August 17, 2007, and is entitled "Class Action Complaint." I shall refer to it hereinafter as the "Complaint."

class of direct purchasers of the drug Arava (the "Class")³, a prescription drug for rheumatoid arthritis, against Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals, Inc. (collectively "Aventis" or "Defendant"). Arava is Aventis's branded version of the drug leflunomide.

Plaintiffs allege that Aventis delayed generic competition by filing a sham Citizen Petition in order to maintain monopoly power in the market for leflunomide. Plaintiffs allege that generic entry was delayed by approximately five-and-a-half months as a result of Defendant's conduct.

III. Assignment

I have been asked to form an opinion about the likely impact of Defendant's conduct on the prices Class members paid for leflunomide. I also have been asked to determine whether the existence of that impact as to all (or nearly all) Class members will be demonstrable without need for individualized inquiry as to the circumstances of individual Class members. Finally, I have been asked to determine whether overcharge damages can be calculated for the Class as a whole on an aggregate basis using a reliable methodology.

³ The "Class" is defined in the Complaint as: "All persons or entities in the United States who purchased 10 mg or 20 mg Arava directly from Aventis (or any of its predecessors or affiliates) at any time from March 2005, until the anticompetitive effects of Defendant's conduct ceased." The Class excludes "Defendant, and its predecessors, its officers, directors, management, employees, subsidiaries, parent or affiliates, and all federal governmental entities." Complaint ¶ 16. I have been informed by counsel that they proposed to change the class definition to include those entities that purchased Arava directly from Aventis at any time from March 2005 to the present.

I have reviewed the Complaint, documents produced in discovery, publicly available data, sales data provided by Aventis and data provided by IMS Health. A list of the materials I and/or my staff have reviewed is attached as Exhibit 2. As discovery is ongoing, I intend to continue reviewing documents and data as they become available. This continued review may lead me to revise or supplement the conclusions set forth herein.

IV. Summary of Conclusions

I have concluded:

1. There is a well-documented history surrounding the competitive effects of unimpeded AB-rated generic competition in pharmaceutical markets generally. This history is reflected in: a) extensive scientific literature regarding the pricing effects of such generic competition; b) Defendant's and generic manufacturers' internal analyses concerning the likely effects of such generic competition on leflunomide prices paid by direct purchasers; and c) pricing data showing the actual experience in dozens of pharmaceutical markets following AB-rated generic entry, including the market for leflunomide once generic competition actually began in September 2005. All of this evidence is common to members of the proposed Class.

2. AB-rated generic competition causes price reductions for the drug molecule facing that competition. As a result, substantial numbers of customers/patients switch their purchases from the brand-name version of the drug to an AB-rated generic equivalent. Direct purchasers, in turn, can and must buy the generic equivalent (at correspondingly lower generic prices) to meet this demand, and be able to supply the customers/patients with the generic equivalent. Accordingly, generic competition (or delayed or impaired AB-rated generic competition) will necessarily impact all (or almost all) direct purchasers.
3. The benefits (*i.e.*, lower prices and/or higher discounts) associated with AB-rated generic competition to any given branded prescription drug product are predictable, substantial and market-wide. As a result, the antitrust impact associated with anticompetitive behavior directed at delaying or preventing generic competition lends itself naturally to class-wide analysis and can be proved on a class-wide basis.
4. Proof of impact (*i.e.*, injury in the antitrust sense) from the Defendant's conduct at issue in this action would consist of the above-mentioned evidence about the substantial size and market-wide scope of generic price impact in general and with respect to

leflunomide in particular, as well as evidence about the direct purchaser's role in the pharmaceutical distribution system and the relationship between market-wide changes in prices and purchase patterns occasioned by AB-rated generic competition. This proof does not require individualized Class member inquiries.

5. The calculation of aggregate overcharges for the Class in this case is readily susceptible to formulaic analysis that does not require individualized inquiry as to each Class member. In the course of my past work, I have had first-hand experience with economic models and methodologies that have reliably measured the aggregate overcharges to classes of direct purchasers alleging delayed or otherwise impaired generic competition. Those methodologies have been accepted by courts presiding over similar pharmaceutical class action cases.⁴ Based upon my review of the data available in this case, I am convinced that a formula drawn from the methods I have used in the past for this same purpose will adequately measure the aggregate overcharge paid by the proposed class in this case.

⁴ See, e.g., In re: Cardizem CD Antitrust Litigation, MDL No. 1278 (E.D. Mich.); In re: Buspirone Patent & Antitrust Litigation, MDL No. 1413 (S.D.N.Y.); In re: Relafen Antitrust Litigation, Master File No. 01-12239-WGY (D. Mass.); In re: Remeron Direct Purchaser Antitrust Litigation, No. 03-CV-0085 (D.N.J.).

V. The Leflunomide Market

A. Arava

Arava is Aventis's branded version of the drug (or "molecule") leflunomide. Leflunomide is a drug prescribed to treat rheumatoid arthritis. Aventis received FDA approval for Arava in 10 mg, 20 mg and 100 mg strengths on September 10, 1998.⁵ The standard dose is 20 mg per day, 10 mg is used in patients who do not tolerate the 20 mg dose, and the 100 mg dose is used for some patients as a "loading dose."⁶

According to the Complaint, under the FDA's regulations, Aventis had the exclusive right to market leflunomide in all three doses for five years.⁷ Aventis also was entitled to "pediatric exclusivity," and was granted an additional six months of exclusivity.⁸ Aventis's exclusivity ended on March 10, 1994.

Sales of Aventis's leflunomide in the United States grew from approximately \$16 million in 1998 to approximately \$226 million in 2004.⁹ Internal Aventis forecasts show that, in the absence of any impediments to generic competition, Aventis expected to lose a substantial portion of its Arava sales to less expensive generic competitors.¹⁰

⁵ FDA Orange Book.

⁶ Complaint ¶¶ 44-45.

⁷ Complaint ¶ 46.

⁸ Complaint ¶ 46.

⁹ Data from IMS Health. IMS Health is a widely-used source of data for the pharmaceutical industry which I and other economists reasonably rely upon in rendering opinions in cases involving impeded generic competition.

¹⁰ See Section VI.B.1. below.

B. Generic Arava

Kali Laboratories, Barr Laboratories, Teva Pharmaceuticals, Apotex Corp. and Sandoz Inc. received FDA approval for their respective AB-rated versions of the 10 mg and 20 mg strengths of leflunomide on September 13, 2005.¹¹ These manufacturers began selling in September 2005.¹² At about that same time, Prasco Laboratories began selling generic leflunomide under a license from Aventis, making use of Aventis's NDA (the sale of a generic under a license from the brand using its NDA is generally referred to as an "authorized generic").¹³ Prior to September 2005, Aventis had been the sole seller of leflunomide in the U.S.¹⁴

C. Generic Competition

In order to obtain an AB-rating from the FDA, a generic drug must be therapeutically equivalent to an existing FDA-approved branded product for that branded product's FDA-approved uses. AB-rated generics provide the same efficacy and safety as their corresponding branded drugs, but at a lower price. AB-rated generics play a critical (and unique) role in U.S. pharmaceutical markets, providing direct, price-related competition to branded drugs.

¹¹ FDA Orange Book.

¹² Data from IMS Health.

¹³ "Prasco Ships Leflunomide Tablets," September 14, 2005 available at <http://www.prasco.com/default.asp?contentID=48> accessed January 2008.

¹⁴ FDA Orange Book.

For AB-rated generics, virtually all of the corresponding brand's market is susceptible to automatic substitution. State laws allow (and in some cases, require) pharmacists to provide patients who have a prescription for the brand product with the less-expensive AB-rated generic.¹⁵ Moreover, when a generic is AB-rated, managed care entities routinely employ mechanisms that result in even more rapid and widespread automatic pharmacy substitution of the AB-rated generic for the corresponding brand.

Under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), products under newly issued NDAs are automatically granted five years of protection from generic competition.¹⁶ After that period has expired, generic drug manufacturers are allowed to file an ANDA, which permits these manufacturers to rely on basic research supporting the safety and efficacy of the original or "pioneer" (i.e., the branded) version of the drug. This offers a shorter and less expensive path to market than a new NDA.

D. Allegations Regarding Defendant's Anticompetitive Conduct

Plaintiffs allege that the Defendant engaged in a scheme to impair and impede generic competition that involved filing a Citizen Petition with the

¹⁵ It is my understanding that in all 50 states, the pharmacist need not obtain the prescribing physician's permission to substitute an AB-rated generic even where the prescription is for the branded version of the drug (unless that prescription is specifically written for "brand only"). By contrast, absent an AB-rating, the pharmacist must first ask and receive permission from a physician to make any contemplated switch to another drug.

¹⁶ There is a five year exclusivity period for new molecular entities.

FDA on the eve of FDA approval of multiple ANDAs for generic leflunomide.¹⁷ The Citizen Petition was filed on March 31, 2005. Without the Citizen Petition, Plaintiffs allege that the generic would have been approved and launched at that time. The FDA found the Citizen Petition was without merit and granted FDA approval for the ANDAs on September 13, 2005.¹⁸ Plaintiffs allege that, as a result of the filing, FDA approval and thus generic entry was delayed by approximately five-and-a-half months. Plaintiffs further claim that Defendant's conduct delayed the competitive benefits (lower prices) that generic competition would have afforded, causing direct purchasers to pay higher prices for leflunomide than they would otherwise have paid.

VI. Antitrust Impact

As an economic matter, conduct that delays (or blocks) generic entry keeps an important source of competition and competitive benefits from entering the market. By so doing, that conduct prevents substitution of a lower-priced generic in place of brand prescriptions. In addition to preventing substitution, delayed generic competition also eliminates any incentive for competitive price reactions by the brand. As a result, direct purchasers pay more for the product needed to fill prescriptions. Where the conduct giving rise to the delay is determined to be illegal, the added cost incurred by direct purchasers is referred to as an overcharge.

¹⁷ Complaint ¶ 7.

¹⁸ Complaint ¶ 7.

Assuming that the conduct at issue in this case was illegal, I expect that all (or nearly all) of the proposed Class members here experienced some amount of overcharge. My conclusion in this regard is grounded in two observations drawn from the empirical evidence and economic literature cited herein about generic competition and the pharmaceutical industry. First, generic competition is a broad and powerful instrument in lowering prices. Typically, within a relatively short time period, unfettered generic competition converts the vast majority of the molecule market to generic products priced at less than a third of what the brand used to command. The remaining few buyers that continue to buy the brand often do so because they are offered substantial discounts.

Second, the Class members in this case (direct purchasers) are, for the most part, middlemen and/or resellers in the drug distribution system, supplying broad cross-sections of the patient community. With substantial numbers of patients/customers substituting the generic for the brand, the substitution-related price reductions that generic competition triggers invariably affect at least some customers/patients supplied by any given direct purchaser. Hence, direct purchasers almost always buy at least some generic product. They may also see increased discounts or lower list (i.e., WAC) prices for their brand purchases as a result of generic entry.¹⁹

¹⁹ In my experience, this often occurs in the rare circumstance of a direct purchaser that buys no generic.

Having now been involved in a number of pharmaceutical cases involving delayed generic competition, I have yet to see a brand subject to unimpeded generic competition for which there was a material number of direct purchasers that were not generic buyers or that did not receive increased discounts from the brand as a result. In other words, illegal delays in generic competition give rise to at least some overcharge--which is to say, antitrust injury--on the part of all (or most all) direct purchasers.

In demonstrating this conclusion, I would offer the following types of evidence. All of it is class-wide in nature.

A. Economic Literature and Empirical Evidence Regarding the Effects of Generic Competition

There is an extensive body of published research concerning the effects of generic competition in pharmaceutical markets. The principal conclusions of this research are that AB-rated generic products: (1) enter the market at substantially lower prices than their branded counterparts; and (2) capture a significant share of the combined product (brand and AB-rated generic) unit sales. Several studies also have found that the price differential between the generic and the corresponding brand, as well as the generic's share of sales, increase over time. Recent work further demonstrates that generic competition produces lower net prices for the brand as well.

Some of the studies that comprise this research include:

1. U.S. Food and Drug Administration, "The Pediatric Exclusivity Provision: January 2001 Status Report to Congress," January 2001.
2. Kirking, D. M., F. J. Ascione, C. A. Gaither, and L. S. Welage, "Economics and Structure of the Generic Pharmaceutical Industry," *Journal of the American Pharmaceutical Association*, 41, 578-584, 2001 ("Kirking, *et al.* (2001)").
3. Congressional Budget Office, "How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry," July 1998 ("CBO Study").
4. Bae, J. B., "Drug Patent Expirations and the Speed of Generic Entry," *Health Services Research*, Vol. 32, No. 1, pp. 87-101, April 1997.
5. Frank, R. and D. Salkever, "Generic Entry and the Pricing of Pharmaceuticals," *Journal of Economics and Management Strategy*, v. 6, no. 1, Spring 1997, pp. 75-90 ("Frank and Salkever (1997)").
6. Grabowski, H. and J. M. Vernon, "Longer Patents for Increased Generic Competition in the US," *PharmacoEconomics*, v. 10, suppl. 2, 1996, pp. 110-123 ("Grabowski and Vernon (1996)").
7. Suh, D., "Effect of Multiple Source Entry on Price Competition After Patent Expiration in the Pharmaceutical Industry," *Health Services Research*, 35:2, June 2000.
8. Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks and Rewards," OTA-H-522, February 1993.
9. Grabowski, H. and J. M. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act," *Journal of Law and Economics*, v. XXXV, October 1992, pp. 331-350 ("Grabowski and Vernon (1992)").
10. Caves, R. E., M. D. Whinston, and M. A. Hurwitz, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers on Economic Activity: Microeconomics*, 1991, pp. 1-66.
11. Scott Morton, F. "Entry Decisions in the Generic Pharmaceutical Industry," *The RAND Journal of Economics*. Vol. 30, no.3, pp. 421-440, 1999.

12. Wiggins, S. N. and R. Maness, "Price Competition in Pharmaceuticals: The Case of Anti-Infectives," *Economic Inquiry*, 2004 ("Wiggins and Maness (2004)").
13. Reiffen, D. and M. Ward, "Generic Drug Industry Dynamics," *The Review of Economics and Statistics*, February 2005, 87(1): 37-49.
14. Saha, A., H. Grabowski, H. Birnbaum, P. Greenberg and O. Bizan, "Generic Competition in the US Pharmaceutical Industry," *International Journal of the Economics of Business*, n. 1, v. 13 (February 2006), pp. 15-38.
15. Gupta, S., Y. Yu and R. Guha, "Pioneering Advantage in Generic Drug Competition," Johnson School Research Paper Series #37-06, August, 2006.

The 1998 CBO Study offers a comprehensive look at the economic effects of generic competition. This study used a large data set, representing about 70 percent of all prescription drugs sold through United States retail pharmacies in 1994. The data set included 21 drugs that faced generic competition between 1991 and 1993. The study found that, "[d]uring the first full calendar year in which those 21 drugs faced generic competition. . . [g]enerics . . . cost one-fourth less than the brand-name drugs, on average, at retail prices."²⁰

The CBO Study also calculated average retail prices for generic and brand pharmaceuticals in 1994. The study reported that the average retail price for a single source drug (*i.e.*, a branded drug with no generic equivalent) was \$53.80 versus \$17.40 for a generic drug, a difference of over 65 percent.²¹

²⁰ CBO Study, p. 28.

²¹ CBO Study, p. 15.

Grabowski and Vernon (1996) compared prices of brand drugs whose patents expired between 1984 and 1991 (the data continued through 1993). The authors found that within one year following generic entry, the generic price fell to less than 50 percent of the brand price. After two years of generic competition, the generic price in each case was less than 40 percent of the brand.

Kirking, *et al.* (2001), reported that the differential between average generic and average brand prescriptions had increased:

In 1993 the average cost for a brandname prescription was about 275% higher than the average generic (\$35.28 versus \$12.82). (cite omitted) By 2000 this difference had grown to nearly 340% (\$65.29 versus \$19.33) (p. 579).

A more recent study by Saha, *et al.* (2006), investigated 40 drugs that experienced generic entry between July 1992 and January 1998. They report that the average price of generics is 76 percent of the brand price a month after generic entry, 54 percent of the brand price a year after generic entry and 41 percent of the brand price two years after generic entry. These authors also report that the generic to brand price ratio decreases approximately 2.3 percent per month with each new generic entrant.

The literature also shows that once generic competition begins, a large portion of the market for the molecule quickly switches over to the generic versions of the product. Within its data set of 21 drugs that faced generic

competition between 1991 and 1993, the CBO found that within the first year, generics captured on average 44 percent of the prescriptions.²² Grabowski and Vernon (1996) support this result and conclude that an analysis of 1991-1992 data shows that within 18 months following entry, the generic market share reached 72 percent of the unit sales of the brand and its generic equivalents. Saha, *et al.* observe a “significant shift away from the brand following the introduction of generic substitutes.” In their sample, the generic captures 14 percent within a month of entry, 43 percent within the first six months and 55 percent by the end of the first year.²³

One additional subject that has frequently been addressed in these studies is the effect of generic entry on prices for the brand. Some early work (Grabowski and Vernon (1992), Frank and Salkever (1997)) observed that even in the face of generic entry, average brand prices continued to increase. However, at the same time, Grabowski and Vernon (1992) found evidence that for some drugs, although brand price *levels* increased, the *rate* of brand price growth decreased with generic entry. A more recent study by Wiggins and Maness (2004) found that brand prices decrease upon generic entry. This result is corroborated by Saha, *et al.* who conclude that “brand prices do respond to

²² CBO Study, p. 28.

²³ Saha, *et al.*, pp. 29-30.

generic competition: each additional entrant on average is associated with a 0.2% decline in brand price.”²⁴

One difficulty with the early work is that it centered on prices drawn from commercially-available data that did not capture all discounts (when compared to the confidential manufacturer transactional data to which I have been given access in numerous cases). The net price paid by direct purchasers for the brand depends both on the starting list price and the discounts they receive. Working with data including discount levels, the CBO Study found that, “[a] statistical analysis of pharmaceutical prices shows that purchasers tend to obtain higher discounts from manufacturers on brand-name drugs when generic substitutes are available[.]”²⁵ The CBO Study concluded that when (as here) two or more generic manufacturers were competing with a brand, discounts off the brand price were 10 to 17 percent greater.²⁶ The CBO Study concluded that “[o]n a selective basis . . . manufacturers of brand name drugs do offer discounts and rebates to some purchasers, and those discounts tend to be larger when generic versions of the drug are available.”²⁷

Overall, this literature clearly establishes that, upon their entry into the market, AB-rated generic drugs sell at a substantial discount to brand drugs

²⁴ Saha, *et al.*, p. 19.

²⁵ CBO Study, p. 24.

²⁶ CBO Study, p. 29.

²⁷ CBO Study, p. 35.

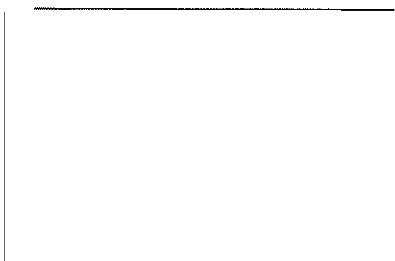
and that the generic price advantage generally continues to grow over time until an equilibrium point is reached. This literature also demonstrates that AB-rated generic products, when not competitively impaired, capture significant unit sales, and hence market share, from their equivalent brand-name products following the inception of generic competition--exactly the sort of powerful substitution effect between AB-rated generics and their corresponding brand-name drugs that Plaintiffs allege has been blocked.²⁸ Recent literature also notes that purchasers are often able to obtain substantially larger discounts and rebates on brand-name drugs following generic entry.

B. The Manufacturers' Internal Generic Penetration Models and Forecasts

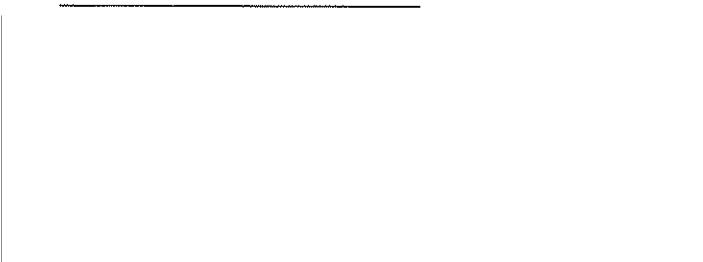
The expected effects of unimpeded AB-rated generic entry (and by contrast the expected effects of the Defendant's exclusionary scheme) were analyzed in a number of Defendant's internal documents and in the documents of would-be generic competitors. These analyses offer another source of evidence that can be used to prove the class-wide impact of Defendant's conduct.

1. Aventis

²⁸ Complaint ¶ 80.



2. Generic Manufacturers



The consistent message from these studies and forecasts is that unimpaired competition from AB-rated generic Arava would have resulted in massive substitution of less expensive generic Arava for the brand, and significantly lower average prices per unit for the leflunomide molecule generally. Thus, to the extent Defendants were able to exclude generic Arava from the market, they were able to forestall these competitive effects--that is to say, Defendants were able to force substantial overcharges broadly across the market. And, here again, this evidence is common to members of the Class.

C. Data Reflecting The Actual Effects of Generic Leflunomide Competition

I have reviewed IMS data on brand sales from Aventis and on generic leflunomide sales that show what happened in the market once the generics arrived.⁴⁰ The significant price difference between Arava and its generic equivalents, combined with the rapid shift in purchases from brand Arava to generic, demonstrates the substantial impact that generic leflunomide entry, and by extension its delay, had on direct purchaser costs. Indeed, this analysis provides a compelling "before and after" study of the kinds of market-wide effects

⁴⁰ Again, IMS Health is a widely-used source of data for the pharmaceutical industry which I and other economists reasonably rely upon in rendering opinions in cases involving impeded generic competition. In my experience, despite some limitations IMS data has, economists and branded and generic drug manufacturers regularly rely on IMS data. The analysis of the IMS data described below can be done with the actual manufacturer data. While I have data from Aventis, I do not yet have data from generic manufacturers. Based upon my experience working both with manufacturers' data and with IMS, I would not expect the qualitative conclusions about the depth and extent of generic pricing effects to be any different based on manufacturer data than are set forth below for the IMS data.

that were delayed as a result of the delay in generic Arava entry, including most importantly for the issues at hand, the generic related reductions in leflunomide costs to direct purchasers.

For instance, in 2005 just before generic entry, Aventis's average net price was approximately \$13.05 per 10 mg tablet. The generics entered in September 2005 at about \$1.92 per tablet, approximately 85% below the brand price. The generic substitution rate for the 10 mg strength was about 82% by the end of 2005 and would reach approximately 96% in 2007.

For the 20 mg strength, Aventis's net average price in 2005 just before generic entry was approximately \$12.91 per tablet. The generic entered in September 2005 at about \$2.25 per tablet, approximately 83% below the brand price. The generic substitution rate, meanwhile, for the 20 mg strength was approximately 79% as of year-end 2005 and approximately 96% in 2007.

D. The Economic Role of Direct Purchasers

From my review thus far of Aventis's computerized sales database, it appears that the direct purchasers of Arava from Aventis were primarily wholesalers, retail pharmacies, and managed care organizations.⁴¹ These entities all supply broad cross-sections of the patient community.

⁴¹ My preliminary analysis of sales data provided by Aventis shows that the Class consists of approximately 42 entities. All of those entities are wholesalers, retail pharmacies and managed care organizations.

As explained above, the impact of the conduct at issue in this case would have been to forestall what would otherwise have been a broad market-wide shift from branded Arava to lower-priced AB-rated generic Arava (through substitution of the generic for the brand), and potentially forestall as well increased discounts on portions of Class members' continuing Arava purchases. Indeed, given that the shift to AB-rated generics replaced approximately 98% of Aventis's Arava prescriptions,⁴² one can reasonably expect that at least some part of that shift would have occurred within the customer base served by each class member.⁴³

Moreover, given the real possibility (based upon the past history of brand pricing responses to generic competition and the academic literature cited above) that at least some of the branded Arava that would have continued to be sold would have carried higher discounts, even the unlikely direct purchaser that would not have purchased any generic even in a fully competitive world may still

⁴² According to IMS data through June 2007.

⁴³ In fact, if one assumes ex ante that each prescription has the same (high) probability of shifting to generics and that those shifts occur independently of one another, the likelihood that a given Class member will see some need to buy generic rapidly approaches one as the volume of its Arava business increases. To illustrate, if every prescription has an independent 70% probability of becoming generic, the likelihood that a direct purchaser/reseller handling 1000 prescriptions would require no generic is $(.3)^{1000}$, which is well below one in a trillion. Even with 50 prescriptions, the probability of a direct purchaser handling no generics is still less than one in a million. While the underlying independence assumption may not hold strictly, there is no reason to believe here that direct purchasers are segmented with respect to their customers in a way that would somehow align the direct purchasers with only non-generic customers (i.e., customers that would have only purchased the brand). In other words, it is extremely likely that all (or almost all) direct purchasers would have needed to supply some number of generic customers if generic Arava had been available.

experience antitrust injury from delayed generic entry through higher Arava prices.⁴⁴

In summary then, the benefits (*i.e.*, lower prices and/or higher discounts) associated with AB-rated generic competition are predictable, substantial and market-wide. As a result, the antitrust impact associated with anticompetitive behavior directed at delaying or preventing generic competition lends itself naturally to class-wide analysis and can be proved on a class-wide basis.

There is a well-documented history surrounding the competitive effects of unimpeded AB-rated generic competition in pharmaceutical markets generally. This history is reflected in: a) extensive scientific literature regarding the pricing effects of such generic competition; b) Defendant's and generic manufacturers' internal analyses concerning the likely effects of such generic competition on leflunomide prices paid by direct purchasers; and c) pricing data showing the actual experience in dozens of pharmaceutical markets following AB-rated generic entry, including the market for leflunomide once generic competition actually began in September 2005. All of this evidence is common to members of the proposed Class.

⁴⁴ In fact, in my experience, one important reason that some entities--managed care in particular--continue to buy the brand in the face of generic entry is price inducements on the part of the brand manufacturer. Accordingly, the likelihood that there is any direct purchaser who would not share directly in lower generic costs increases hand-in-hand with the likelihood of generic-related brand price affects.

AB-rated generic competition causes price reductions for the drug molecule facing that competition. As a result, substantial numbers of customers/patients switch their purchases from the brand-name drug to the AB-rated generic equivalent. Direct purchasers, in turn, can and must buy the generic equivalent (at correspondingly lower generic prices) to meet this demand, and be able to supply the customers/patients with the generic equivalent. Accordingly, generic competition (or delayed or impaired AB-rated generic competition) will necessarily impact all (or almost all) direct purchasers.

Proof of impact (i.e., injury in the antitrust sense) from the Defendant's conduct at issue in this action would consist of the above-mentioned evidence about the substantial size and market-wide scope of generic price impact in general and with respect to leflunomide in particular, as well as evidence about the direct purchaser's role in the pharmaceutical distribution system and the relationship between market-wide changes in prices and purchase patterns occasioned by AB-rated generic competition. This proof does not require individualized Class member inquiries.

VII. Class-Wide Analysis of Damages

Plaintiffs claim that they and members of the Class were harmed by Defendant's allegedly unlawful conduct by paying more for leflunomide during the period in which generic competition was allegedly delayed by Defendant's

conduct, and for some period thereafter until the competitive process reaches the equilibrium it would have achieved had generic competition not been delayed. For purposes of measuring the damages associated with these claims, my understanding is that Plaintiffs need only assess the aggregate overcharge suffered by the Class collectively. The allocation of any recovery as to individual Class members is reserved for post-trial (or settlement) proceedings.

I take confidence in my ability to measure aggregate overcharges suffered by the Class members in this action from my experience in similar cases. Among others, I have analyzed overcharges for direct purchaser classes of the products Cardizem, Buspar, Relafen, Remeron, Tricor, Nifedipine and Ovcon. In many of these cases, the aggregate damage analysis I performed served as the basis for the court's review and approval of class-wide settlements. My review of the facts in this case reveals nothing to indicate that overcharges will not be similarly susceptible to class-wide measurement.

Overcharge damages arise from the difference between the actual prices that Class members paid for leflunomide and the prices they would have paid had generic leflunomide entered the market earlier. While data reflecting actual prices, market shares, and purchase volumes are available, these same quantities have to be estimated in the but-for world involving earlier generic entry dates.

The method I have employed frequently in those cases (and the method I would apply here) to measure aggregate overcharges to the Class involves, first, the development of a benchmark for market performance--the "but-for world"--reflecting the world as it would have existed had generic competition not been restrained by Defendant's conduct. The next step involves a comparison of the Class members' aggregate purchase costs for the drug (including both branded and generic forms) as between their actual experience and the experience they would have had in the but-for world.

But-for prices can be measured using a "before/after" method.⁴⁵ The before/after method uses the market experience before and/or after the alleged misconduct period to provide the basis for estimating prices that would have existed during the period but for the conduct in question. I have used this approach to measure but-for prices in the past. The introduction of generic leflunomide to the market in September 2005 marks the start of an "after" period with market results that reasonably portray what would have happened to prices but for the delay in generic entry.⁴⁶

To use the post-generic entry experience as the benchmark for calculating overcharges, I take that pricing experience as it actually occurred and, as a general matter, simply shift it back to the point in time at which it would

⁴⁵ See Hovenkamp, Herbert, *Federal Antitrust Policy: The Law of Competition and Its Practice*, 2nd ed., St. Paul, MN: West Group, 1999, pp. 660-6.

⁴⁶ I expect discovery in this case to yield class-wide transactional data from this "after" period.

have occurred but for the alleged anticompetitive conduct. In that way, my analysis of the but-for world directly reflects real world pricing data and experience. I utilize pricing data from the same manufacturers, the same product, and essentially the same customers that would have made up the leflunomide market but for the alleged delay in generic entry. It provides a reliable basis for reconstructing leflunomide prices in the but-for world.

To measure the aggregate damages to Class members as a whole, I calculate the difference over the damages period between the average price the Class actually paid for leflunomide products (brand plus generics) and the average price that the Class would have paid for those products in the but-for world. I then multiply that difference by the volume of leflunomide in the but-for world.

Overall, these overcharges can be assessed readily through class-wide, aggregate damage models utilizing formulas and methodologies that do not require individualized analysis.

I am signing this Declaration under penalty of perjury.

Date: January 29, 2008


Jeffrey J. Leitzinger, Ph.D.



Dr. JEFFREY J. LEITZINGER
President
Los Angeles, California
Tel: 213 624 9600

EDUCATION

Ph.D., Economics, University of California, Los Angeles
M.A., Economics, University of California, Los Angeles
B.S., Economics, Santa Clara University

WORK EXPERIENCE

Econ One Research, Inc., President, July 1997 to date
Founded *Econ One Research, Inc.*, 1997

Micronomics, Inc., President and CEO, 1994-1997
Micronomics, Inc., Executive Vice President, 1988-1994
Cofounded *Micronomics, Inc.*, 1988

National Economic Research Associates, Inc. 1980-1988
(Last position was Senior Vice President and member of the Board of Directors)

ADMITTED AS AN EXPERT ECONOMIST TO TESTIFY ABOUT:

Relevant Markets and Competition

Before: Federal Energy Regulatory Commission
Superior Court, State of Alaska
Superior Court, State of California
Superior Court, State of Washington
U.S. District Court, Central District of California
U.S. District Court, Northern District of California
U.S. District Court, District of Colorado
U.S. District Court, Eastern District of Missouri
U.S. District Court, Eastern District of Texas
U.S. District Court, Western District of Texas
U.S. District Court, District of Wyoming

Valuation, Economic Loss and Damages

Before: Circuit Court, Mobile County, Alabama
Civil Court, Harris County, Texas

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President

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Civil Court, Midland County, Texas
State of Alaska Department of Revenue
Superior Court, State of California
U.S. Bankruptcy Court, District of Alaska
U.S. Bankruptcy Court, Northern District of Texas
U.S. District Court, State of Alabama
U.S. District Court, Central District of California
U.S. District Court, District of Colorado
U.S. District Court, State of Louisiana
U.S. District Court, Southern District of Mississippi
U.S. District Court, District of North Dakota
U.S. District Court, Eastern District of Texas
U.S. District Court, Southern District of Texas
U.S. District Court, Western District of Texas

Patent and Intellectual Property Issues

Before: Superior Court, State of Washington
U.S. District Court, Northern District of California
U.S. District Court, District of Colorado
U.S. District Court, District of Connecticut
U.S. District Court, Southern District of Texas

The Economics of Regulated Industries

Before: Alaska Public Utilities Commission
California Energy Commission
California Public Utilities Commission
Federal Energy Regulatory Commission
Nevada Public Service Commission
Wisconsin Public Service Commission
U.S. District Court, Northern District of Oklahoma
U.S. District Court, Northern District of Texas

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Dr. Jeffrey J. Leitzinger
President

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President

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Dr. Jeffrey J. Leitzinger
President

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President

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Econ One Research, Inc.
Los Angeles, California

DR. JEFFREY J. LEITZINGER
Prior Testimony
January 2004 – January 2008

Proceeding	Court/Commission/Agency	Docket or File	Deposition/ Trial/Hearing	Date
1. <u>In Re: Terazosin Hydrochloride Antitrust Litigation</u>	U.S. District Court, Southern District of Florida	Case Nos. 98-3125 and 99-7134	Deposition	January 2002 July 2002 February 2004
2. <u>In Re: Ciprofloxacin Hydrochloride Antitrust Litigation</u>	U.S. District Court, Eastern District of New York	No. 1:00-MD-1383	Deposition	July 2003 May 2004
3. <u>In Re: Scrap Metal Antitrust Litigation</u>	U.S. District Court, Northern District of Ohio, Eastern Division	No. 1:02 CV 0844	Deposition Trial	August 2003 September 2004 January 2006
4. <u>Chevron U.S.A., Inc. v. State of Louisiana, Louisiana State Mineral Board, and Louisiana Department of Natural Resources</u>	U.S. District Court, 17 th Judicial District, Parish of Lafourche, Louisiana	Number 93,658 Division C	Deposition Trial	January 2004 March 2004
5. <u>Houston McLane Co., Inc. and Houston Regional Sports Network, L.P., v. Affiliated Regional Communications, Ltd.</u>	U.S. District Court, 333 rd Judicial District, Harris County, Texas	Cause No. 2003-10943	Deposition	March 2004

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Econ One Research, Inc.
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DR. JEFFREY J. LEITZINGER
Prior Testimony
January 2004 – January 2008

Proceeding	Court/Commission/Agency	Docket or File	Deposition/Trial/Hearing	Date
6. <u>Harry E. Stetser, Dale E. Nelson & Michael deMontbrun v. TAP Pharmaceutical Products, Inc., et al</u>	State of North Carolina, New Hanover County, In The General Court of Justice, Superior Court Division	File No. 01CVS 5268	Deposition	April 2004
7. <u>Masimo Corporation, vs. Tyco Health Care Group L.P., and Mallinckrodt, Incorporated</u>	U.S. District Court, Central District of California, Western Division	Case No. CV-02-4770	Deposition Trial	April 2004 March 2005
8. <u>J.B.D.L. Corp. d/b/a Beckett Apothecary, et al. v. Wyeth-Ayerst Laboratories, Inc., et al.</u>	United States District Court, Southern District of Ohio, Western Division	Civil Action No. C-1-01-704	Deposition	May 2004 November 2004
9. <u>Dewana G. Turner, Bonita H. Hixson, and Yolanda P. Monroe, on behalf of themselves and all others similarly situated v. Alaska Communications Systems Long Distance, Inc., and Alaska Communications Systems Group, Inc.</u>	Superior Court for the State of Alaska, Third Judicial District at Anchorage	Case No. 3AN-01-7208 CI	Deposition	July 2004

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DR. JEFFREY J. LEITZINGER
Prior Testimony
January 2004 – January 2008

Proceeding	Court/Commission/Agency	Docket or File	Deposition/ Trial/Hearing	Date
10. <u>In Re: Remeron Direct Purchaser Antitrust Litigation</u>	U.S. District Court, District of New Jersey	Master Docket No. 03-CV-0085	Deposition	July 2004
11. <u>Louisiana Wholesale Drug Co., Inc., on behalf of itself and all others similarly situated, v. Schering-Plough Corporation; Upsher-Smith Laboratories; and American Home Products Corporation</u>	U.S. District Court, District of New Jersey	MDL No. 1419	Deposition	December 2004
12. <u>Pixion, Inc., v. Placeware, Inc.</u>	U.S. District Court, Northern District of California	Case No. C 03 2909 SI	Deposition Trial	December 2004 February 2005
13. <u>Fran-Am Partnership, L.L.C. vs. Sports Car Club of America, Inc. and S.C.C.A. Enterprises, Inc.</u>	U.S. District Court, District of Colorado	Civil Action No. 02-Z-2060 (OES)	Deposition	January 2005
14. <u>In Re: Medical Waste Services Antitrust Litigation</u>	U.S. District Court, District of Utah, Central Division	MDL No. 1546	Deposition	April 2005

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Econ One Research, Inc.
Los Angeles, California

DR. JEFFREY J. LEITZINGER
Prior Testimony
January 2004 – January 2008

Proceeding	Court/Commission/Agency	Docket or File	Deposition/ Trial/Hearing	Date
15. <u>Applied Medical Resources Corp. v. Ethicon, Inc. Ethicon Endosurgery, Inc., et al.</u>	U.S. District Court, Central District of California, Southern Division	Case NO. SACV 03-1329 JVS	Deposition Trial	June 2005 August 2006
16. <u>Brady Enterprises, Inc.; Charlotte J. Lopacki, d/b/a Budget Drug and Heritage Pharmacy, Inc.; On behalf of themselves and all others similarly situated, and the Pharmacy Freedom Fund and the National Community Pharmacists Association v. Medco Health Solutions, Inc., et al.</u>	U.S. District Court, Eastern District of Pennsylvania	Civil Action No. 03-4730	Deposition	July 2005
17. <u>The Regents of the University of California, a CA Public corporation, vs. Monsanto Company, a Delaware Corp.</u>	U.S. District Court, Northern District of California, San Francisco Division	Case No. C04-00634 PJH	Deposition	August 2005
18. <u>Dennis M. Devetter, vs. Alex. Brown Management Services, Inc., et al.</u>	In the Circuit Court for Baltimore City	Case No. 24-C-037514	Deposition	January 2006

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Econ One Research, Inc.
Los Angeles, California

DR. JEFFREY J. LEITZINGER
Prior Testimony
January 2004 – January 2008

Proceeding	Court/Commission/Agency	Docket or File	Deposition/ Trial/Hearing	Date
19. <u>Sky Technologies, LLC, vs. IBM Corporation and i2 Technologies, Inc.</u>	U.S. District Court, Eastern District of Texas, Marshall Division	Case No. 2:03 CV 54-DF	Deposition	January 2006
20. <u>In Re: Nifedipine Antitrust Litigation</u>	U.S. District Court, District of Columbia	MDL No. 151	Deposition	May 2006
21. <u>In Re: Tricor Direct Purchaser Antitrust Litigation</u>	U.S. District Court, District of Delaware	Civil Action No. 05-340 KAJ	Deposition	July 2006
22. <u>Tessera, Inc. v. Micron Technology, Inc., Micron Semiconductor Products, Inc., Infineon Technologies AG, Infineon Technologies Richmond, LP, Infineon Technologies North America Corp., and Qimonda AG</u>	U.S. District Court, Eastern District of Texas	Case No. 2:05-CV-94	Deposition	July 2006
23. <u>The SCO Group v. International Business Machines Corporation</u>	U.S. District Court, District of Utah	Civil No. 2:03CV-0294	Deposition	September 2006

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Econ One Research, Inc.
Los Angeles, California

DR. JEFFREY J. LEITZINGER
Prior Testimony
January 2004 – January 2008

Proceeding	Court/Commission/Agency	Docket or File	Deposition/ Trial/Hearing	Date
24. <u>USJ of Southern California, et al., v. Christopher Rodenfels</u>	Superior Court of the State of California, for the County of Los Angeles, Central District	Case No. BC335639	Deposition	November 2006
25. <u>Columbus Drywall & Insulation, Inc., et al., on behalf of a class of similarly situated persons v. Masco Corporation, et al.</u>	U.S. District Court, Northern District of Georgia, Atlanta Division	Civil Action No. 1:04-cv-3066	Deposition Deposition	November 2006 February 2007
26. <u>John G. Miles, et al. v. Merrill Lynch & Co., et al.</u>	United States Court of Appeals for the Second Circuit	Docket No. 05-3349-cv	Trial	December 2006
27. <u>City of San Antonio, Texas, et al. v. Hotels.com, LP, et al.</u>	U.S. District Court, Western District of Texas, San Antonio Division	Case No. SA06CA0381 OG	Deposition Hearing	March 2007 May 2007

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Econ One Research, Inc.
Los Angeles, California

DR. JEFFREY J. LEITZINGER
Prior Testimony
January 2004 – January 2008

Proceeding	Court/Commission/Agency	Docket or File	Deposition/ Trial/Hearing	Date
28. <u>Meijer, Inc. and Meijer Distribution, Inc., on behalf of themselves and all others similarly situated v. Warner Chilcott Holdings Company III, Ltd., et al.</u>	U.S. District Court, District of Columbia	Civil Action No. 1:05-CV-02195-CKK	Deposition	April 2007
29. <u>Funeral Consumers Alliance, Inc., et al., v. Service Corporation International, et al.</u>	U.S. District Court, District of Southern District of Texas, Huston Division	Civil Action No. 4:05-CV-03394 Civil Action No. 4:05-CV-03399	Deposition	August 2007

Exhibit 2

**Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis, Sanofi-Aventis U.S., LLC and Aventis Pharmaceuticals, Inc.
List of Materials Reviewed**

Includes all documents, studies, and articles cited in the Declaration.

Pleadings

Class Action Complaint (8-17-2007)

Documents APIA prefix

00100000387
00100000828
00100000835
00100000838
00100000864
00600000089 - 0397
00600000127 - 0146
00600000252
00600000236 - 0238
00700000140 - 0177
00700000180 - 0185
00700000192 - 0201
00700000346 - 0347
00700000396 - 0397
00700000441
00700000470
00700000508 - 0509
00800005567
00800009748 - 9749
00800009863 - 9864
01900000550 - 0551

Documents APOTEX prefix

0061 - 0070

Documents KALILEF prefix

000912 - 000938
000940
000943 - 00968

Documents Prasco(LEF) prefix

000119 - 0122
000156 - 0158
000162 - 0175
000196 - 000209

Documents Sandoz prefix

001336 - 001350

Documents no prefix

Arava Price Revision June 2005

Data - Electronic Files/CDs

Aventis

APIT000002.xls
ARAVA_1267_chgbks_extr_20071128.csv
ARAVA_1267_customer_extr_20071128.csv
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IMS Health

IMS Health NSP data 1992-2007
IMS Health NPA data 2002-2007

Exhibit 2

**Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis, Sanofi-Aventis U.S., LLC and Aventis Pharmaceuticals, Inc.
List of Materials Reviewed**

Publicly Available Materials

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CERTIFICATE OF SERVICE

I, Anne K. Fornecker, do hereby certify that on January 31, 2008, I served the foregoing DECLARATION OF JEFFREY J. LEITZINGER, PH.D. on the following attorneys, in the manner specified below:

Via First Class and Electronic Mail:

JONES DAY
Julia E. McEvoy
Christopher R. Farrell
Rosanna K. McCalips
51 Louisiana Avenue, NW
Washington DC 20001
Tel: 202-879-3939
Fax: 202-626-1700
jmcevoy@jonesday.com
crfarrell@jonesday.com
rkmccalips@jonesday.com

JONES DAY
Samuel Joseph Hand
222 East 41st Street
New York, New York 10017-6702
Tel: 212-326-3939
Fax: 212-755-7306
jhand@jonesday.com

*Attorneys for Defendants sanofi-aventis,
sanofi-aventis u.s. llc, and Aventis
Pharmaceuticals, Inc.*

Via Electronic Mail:

KAPLAN, FOX & KILSHEIMER, LLP
Linda Nussbaum
Richard Kilsheimer
850 Third Avenue, 14th Floor
New York, NY 10022
Tel: (212) 687-1980
rkilsheimer@kaplanfox.com
lnussbaum@kaplanfox.com

KOZYAK, TROPIN & THROCKMORTON

Adam Moskowitz
Tucker Ronzetti
2525 Ponce de Leon Blvd., 9th Floor
Miami, FL 33134
Tel: (305) 372-1800
amm@kttl.com
tr@kttl.com

ODOM & DES ROCHES, LLP

John Gregory Odom
Stuart E. Des Roches
Charles F. Zimmer, II
Suite 2020, Poydras Center
650 Poydras Street
New Orleans, LA 70130
Tel: (504) 522-0077
Fax: (504) 522-0078
stuart@odrlaw.com
czimmer@odrlaw.com

BERGER & MONTAGUE, P.C.

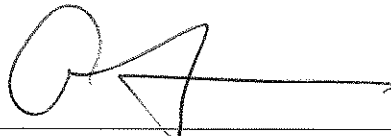
Daniel Berger
David F. Sorensen
Peter R. Kohn
1622 Locust Street
Philadelphia, PA 19103
Tel: 1-800-424-6690
Fax: (215) 875-4604
dsorensen@bm.net
pkohn@bm.net

PERCY, SMITH & FOOTE, LLP

W. Ross Foote
Susan C. Segura
720 Murray Street
P.O. Box 1632
Alexandria, LA 71309-1632
Tel: (318) 445-4480
Fax: (318) 487-1741
rfoote@psflp.com
sssegura@psflp.com

PHELPS DUNBAR
Brent Barriere
Susie Morgan
Canal Place, Suite 2000
365 Canal Street
New Orleans, LA 70130-6534
Tel: 504-568-1311
Fax: 568-9130
susie.morgan@phelps.com

*Attorneys for Plaintiff Louisiana Wholesale
Drug Co., Inc.*

A handwritten signature in black ink, appearing to read 'Anne K. Fornecker', with a long horizontal line extending to the right.

ANNE K. FORNECKER (AF-2073)
Garwin Gerstein & Fisher LLP
1501 Broadway, Suite 1416
New York, New York 10036
(Tel): 212-398-0055
(Fax): 212-764-6620
afornecker@garwingerstein.com